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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CHERI LEONARD, on behalf of herself and all others similarly situated,

Plaintiff,

v.

CVS PHARMACY, INC., AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and AMNEAL PHARMACEUTICALS LLC,

Defendants.

Case No. 5:24-cv-06280-EJD

FIRST AMENDED CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Hon. Edward J. Davila

Plaintiff Cheri Leonard ("Plaintiff"), individually and on behalf of all others similarly situated, alleges the following on information and belief, except that Plaintiff's allegations as to her own actions are based on personal knowledge:

NATURE OF THE ACTION

1. This is a class action lawsuit regarding Defendants CVS Pharmacy, Inc.'s ("CVS"), Amneal Pharmaceuticals of New York, LLC's, and Amneal Pharmaceuticals, LLC's (collectively "Amneal") (CVS and Amneal are collectively referred to as "Defendants") manufacturing, distribution, and sale of guaifenesin-containing medications with an inactive ingredient carbomer manufactured by Defendant Amneal that contains dangerously high levels of benzene, a carcinogenic impurity that has been linked to leukemia, lymphoma, and other cancers.

2. The guaifenesin-containing medications include generic versions of the brand-name drug Mucinex. The products at issue in this matter are all over-the-counter medications sold by CVS and manufactured by Amneal containing the inactive ingredient carbomer, including: (1) CVS-branded Maximum Strength Mucus Extended Release, Guaifenesin Extended-Release Tablets, 1200 mg; (2) CVS-branded Mucus Extended Release, Guaifenesin Extended-Release Tablets, 600 mg; (3) CVS Health 12HR Maximum Strength Mucus DM Extended Release Tablets, 1200mg/60mg; (4) CVS Health 12HR Mucus DM Extended Release Cough Tablets, 600mg/30mg; and (5) CVS Health 12HR Maximum Strength Cough and Congestion Relief Extended Release Tablets (the "Products").

3. Carbomer is an inactive ingredient in both brand name Mucinex as well as its generic formulations, including the Products manufactured and sold by Defendants. In fact, Defendants specifically represent that the Products should be "compare[d] to the active ingredient in … Mucinex":

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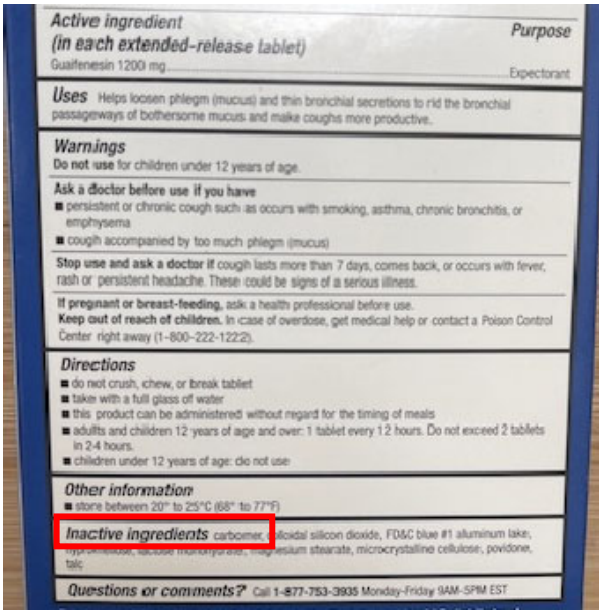

4. However, there is a significant difference between Mucinex and its generic counterparts like the Products. Specifically, the carbomer used in brand name Mucinex *does not* contain benzene, but the carbomer included in the Products *does contain* benzene. And the level of benzene contamination in these carbomer formulations can be astronomically high, including as high as 5,000 parts per million ("ppm"). For reference, the guidance for the upper limit for benzene as an impurity is 2 ppm.

5. Benzene is a component of crude oil, gasoline, and cigarette smoke, and is one of the elementary petrochemicals. The Department of Health and Human Services has determined that benzene causes cancer in humans, and benzene is associated with blood cancers such as leukemia. Likewise, the Food and Drug Administration ("FDA") lists benzene as a "Class 1 solvent" that "should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity."[1]

6. Crucially, there is no reason for the Products to contain benzene (*i.e.*, the use of benzene in the manufacturing process in the Products is not "unavoidable"). Indeed, brand-name Mucinex is manufactured without a carbomer (and thus, the finished product) containing benzene.

[1] https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs.

But the reason Defendants use benzene in the manufacturing process of the Products is simple: it is cheaper to use a carbomer manufactured using benzene.[2]

7. Said another way, Defendants used an inferior (and dangerous) carbomer formulated with benzene to increase its bottom line while exposing Plaintiffs and Class members to benzene in the Products.

8. There was no impediment to Defendants using a different carbomer that did not contain benzene, and therefore, Defendant could have addressed the issue without running into any express or implied conflict between its federal and state law obligations. Defendants did not need to change the Products' labels to remedy the unlawful conduct, they simply had to change the carbomer to one that does not contain benzene (which is what Amneal is currently doing following the FDA's December 2023 guidance forbidding the use of carbomers formulated using benzene as a solvent[3]).

9. Amneal has admitted that finished doses of the Products contain benzene, and has also admitted that it is in the process of reformulating the Products to comply with the aforementioned FDA guidance. Amneal's admission, as well as the fact that it is reformulating the Product, plausibly establishes that *every* Product manufactured and sold by Defendants contains benzene as a result of the Products' formulation process because Amneal used carbomers that were formulated with benzene, even though alternative carbomers exist that do not contain or utilize benzene in the manufacturing process.

10. Defendants did not disclose to consumers, including Plaintiff and Class Members, that either the carbomer used in the manufacturing of the Products or the finished Products themselves contained benzene. And "nothing in the FDCA prohibits Defendant from[s] disclosing the presence of benzene or a warning regarding its cancer-causing properties elsewhere on [the

[2] Alisa Chang et al., *Millions of Americans May be Getting Cancer-Causing Chemical in Generic Cold Medicine*, NPR (Aug. 16, 2024), https://www.npr.org/2024/08/16/nx-s1-5077764/millions-of-americans-may-be-getting-cancer-causing-chemical-in-generic-cold-medicine.

[3] The FDA's Guidance entitled "Reformulating Drug Products That Contain Carbomers Manufactured With Benzene" is available at https://www.regulations.gov/document/FDA-2023-D-5408-0002 (last visited 1/17/25).

Products'] label." *Henning v. Luxury Brand Partners, LLP*, 2023 WL 3555998, at *6 (N.D. Cal. May 11, 2023).

11. Had Defendants disclosed that the Products contained benzene, and/or disclosed the cancer-causing properties to Plaintiff and Class Members, Plaintiff and Class Members would not have purchased the Products or would have paid less for the Products than they did but for Defendants' omissions. Similarly, had Defendants disclosed that the manufacturing process for the Products utilized a carbomer formulated with benzene, Plaintiff and Class Members would not have purchased the Products or would have paid less for the Products than they did but for Defendants' omissions.

12. In fact, Defendants likely could not have sold the Products had it disclosed the use of benzene in the Products' formulation because the presence of benzene renders the Products adulterated, misbranded, and illegal to sell.

13. Plaintiff brings this action on behalf of herself and a proposed class for damages for: (i) breach of the implied warranty of merchantability, (ii) unjust enrichment, (iii) fraud, (iv) violation of California's Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*, and (v) violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq*.

THE PARTIES

14. Plaintiff Cheri Leonard is a resident of Ben Lomond, California. In approximately July 2024, Plaintiff purchased CVS-branded Maximum Strength Mucus Extended Release, Guaifenesin Extended-Release Tablets, 1200 mg from a CVS retail location in Felton, California. When purchasing the product, Plaintiff reviewed the accompanying labels and disclosures and understood them as representations and warranties by Defendants that the product was properly manufactured, free from defects (including carcinogenic impurities such as benzene), safe for its intended use, not misbranded, and legal to sell. The Product contained no representation that it contained benzene. Instead, the label simply lists "carbomer" as an inactive ingredient with no indication that benzene was used in the formulation of the carbomer and contaminated the finished product. Plaintiff relied on these representations and warranties in deciding to purchase the product

manufactured and sold by Defendants, and these representations and warranties were part of the basis of the bargain in that she would not have purchased the product from Defendants or would have paid less for it had she known that benzene was used in the formulation of the Product, and that the Product was not properly manufactured and free from defects like the benzene contamination. Moreover, the presence of avoidable and unsafe levels of benzene in the Product rendered it unsafe to use, worthless, and illegal to sell. Accordingly, Plaintiff was injured and lost money as a result of Defendants' deceptive and unfair conduct.

15. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with a principal place of business located at One CVS Drive, Woonsocket, Rhode Island 02895. CVS is a retail pharmacy chain with over 9,000 locations throughout the United States, hundreds of which are located in California.[4] CVS Pharmacy sells the Products throughout the United States, including in the State of California. The Products, including those purchased by Plaintiff and Class members, are available at CVS retail locations throughout the United States, including in the State of California. CVS Pharmacy authorized the false, misleading, and deceptive marketing, advertising, distribution, and sale of the Products.

16. Defendant Amneal Pharmaceuticals of New York, LLC is a limited liability company formed under the laws of Delaware with a principal place of business at 85 Adams Avenue, Hauppauge, New York 11788. Amneal conducts substantial business in the United States, and specifically in the State of California. Amneal has been engaged in the manufacturing of the Products in the United States, including in the State of California.

17. Defendant Amneal Pharmaceuticals LLC is a corporation incorporated under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807. Amneal conducts substantial business in the United States, and specifically in the State of California. Amneal has been engaged in the manufacturing of the Products in the United States, including in the State of California.

[4] https://www.cvs.com/store-locator/cvs-pharmacy-locations/California

18. The Amneal Defendants are a global pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceuticals to chain pharmacies, such as CVS, as is the case with the Products in this matter.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendants, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

20. This Court has specific personal jurisdiction over Defendants because Defendants have purposely directed their conduct to the California forum and this action arises out of and relates to Defendants' contacts with this forum.

21. Specifically, Defendant Amneal knowingly placed the Products into the stream of commerce directed into California. As confirmed in Defendants' Declaration of Andrew Boyer In Support of Defendants' Motion to Dismiss Plaintiff's Class Action Complaint ("Boyer Decl."), Defendant Amneal "sells and ships the Products that it manufactures exclusively to a distributor in New York, P & L Development, LLC … pursuant to a Supply Agreement." *See* EFC No. 21-1; 21-2.

22. Because Amneal exclusively sells and ships the Products to this distributor, Amneal knows, or should know, of the distributor's locations, such as their manufacturing, distribution, and packaging facilities. Therefore, Amneal knows or should know that P & L Development, LLC operates manufacturing, packaging, and distribution facilities in California—meaning Products Amneal sells exclusively to P & L Development, LLC must reach California.[5] In fact, California is one of only four states in which P & L Development, LLC operates, meaning *it is one of the four states* that receives the Products Amneal sells.[6]

[5] PL DEVELOPMENTS, *Locations*, http://www.pldevelopments.com/about/locations/.

[6] *See id.*

23. In sum, Amneal exclusively uses the distributor P & L Development, LLC to put the Product in the market and this distributor uses California as one of its four bases of distribution. Therefore, by contracting to exclusively sell and therefore distribute its Product via P & L Development, LLC, Amneal is purposefully directing the Product to California.

24. Further, Defendants have advertised and marketed within California through the wires and mail and via e-commerce websites through which residents of California can purchase the Products. In addition, Defendants knowingly direct electronic activity into California with the intent to engage in business interactions and have in fact engaged in such interactions.

25. Plaintiff's claims arise out of Amneal's contacts with the forum because Plaintiff purchased her Product from a CVS in Ben Lomond, California. This means that Amneal sold the Product that Plaintiff purchased to P & L Development, LLC, and that Product was subsequently distributed from P & L Development, LLC 's California distribution center to the CVS in Ben Lomond, California from which Plaintiff purchased the Product. But for Amneal selling the Product to a distributor that operates in California, Plaintiff would not have had the Product available for purchase and would not have purchased the Product and suffered the harm described herein.

26. CVS also consented to personal jurisdiction in California because, at all times material to this action, it was registered to do business in California and appointed a registered agent for service of process in California.

27. Amneal consented to personal jurisdiction in California because, at all times material to this action, it was registered to do business in California and appointed a registered agent for service of process in California.

28. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims took place within this District. Specifically, Plaintiff purchased the CVS-branded Maximum Strength Mucus Extended Release, Guaifenesin Extended-Release Tablets, 1200 mg Product in this District.

FACTS COMMON TO ALL CLASS MEMBERS

I. BENZENE IS A KNOWN HUMAN CARCINOGEN

29. Benzene is a component of crude oil, gasoline, and cigarette smoke, and is one of the elementary petrochemicals.[7] The Department of Health and Human Services has determined that benzene causes cancer in humans. Likewise, the Food and Drug Administration ("FDA") lists benzene as a "Class 1 solvent" (*i.e.*, a solvent that should be avoided) that "should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity."

30. Benzene is associated with blood cancers such as leukemia.[8] A study from 1939 on benzene stated that "exposure over a long period of time to any concentration of benzene greater than zero is not safe."[9] This comment was reiterated in a 2010 review of benzene research, which specifically stated: "There is probably no safe level of exposure to benzene, and all exposures constitute some risk in a linear, if not supralinear, and additive fashion."[10]

31. According to the American Cancer Society:

> [The International Agency for Research on Cancer] classifies benzene as "carcinogenic to humans," based on sufficient evidence that benzene causes acute myeloid leukemia (AML). IARC also notes that benzene exposure has been linked with acute lymphocytic leukemia (ALL), chronic lymphocytic leukemia (CLL), multiple myeloma, and non-Hodgkin lymphoma.[11]

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[7] "Petrochemicals are products derived from oil and natural gas, and include plastics, soaps, detergents, fertilisers, solvents, drugs, pesticides, synthetic fibres and rubbers, paints and insulating materials." OVERVIEW OF THE GLOBAL PETROCHEMICAL INDUSTRY (May 13, 2024), https://zerocarbon-analytics.org/archives/energy/overview-of-the-global-petrochemical-industry.

[8] NATIONAL CANCER INSTITUTE, CANCER-CAUSING SUBSTANCES, BENZENE, https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene.

[9] F.T. Hunter, *Chronic Exposure to Benzene (Benzol). II. The Clinical Effects*, 21 JOURNAL OF INDUSTRIAL HYGIENE AND TOXICOLOGY 331 (1939), https://www.cabdirect.org/cabdirect/abstract/19402700388.

[10] Martyn T. Smith, *Advances in Understanding Benzene Health Effects and Susceptibility*, 31 ANNUAL REVIEW OF PUBLIC HEALTH 133 (2010), https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.012809.103646.

[11] AMERICAN CANCER SOCIETY., BENZENE AND CANCER RISK (January 5, 2016) (), https://www.cancer.org/cancer/cancer-causes/benzene.html).

32. According to the National Institute for Occupational Safety and Health, humans can become exposed to benzene through "inhalation, skin absorption, ***ingestion***, skin and/or eye contact."[12]

33. The CDC warns that "[b]enzene works by causing cells not to work correctly. For example, it can cause bone marrow not to produce enough red blood cells, which can lead to anemia. Also, it can damage the immune system by changing blood levels of antibodies and causing the loss of white blood cells."[13]

34. The FDA has stated that if the use of benzene is "*unavoidable* to produce a drug product with a significant therapeutic advance, then its levels should be restricted to 2 parts per million (ppm), unless otherwise justified." In general, however, "solvents such as benzene should not be employed in the manufacture of drug substances, excipients, or drug products because of their unacceptable toxicity."[14]

35. Since at least 2021, a number of drug and cosmetic products have been found to contain benzene and have been recalled accordingly. These have included sunscreens, antiperspirant products, and dry shampoos.

II. CARBOMERS USED IN THE PRODUCTS ARE FORMULATED WITH BENZENE

36. The benzene contamination in the Products derives from the use of the inactive ingredient carbomer. Carbomers are "are a group of polymers composed of acrylic acid" that are "widely used as inactive ingredients in drug products as fillers, emulsifiers, gelling agents, and binding agents."[15] In plain English, carbomers are used for purposes such as giving medicines "a clear, gel-like consistency" and gives products "a longer shelf life." If one has ever noticed that

[12] National Institute for Occupational Safety and Health (NIOSH), Benzene, https://www.cdc.gov/niosh/npg/npgd0049.html.

[13] BENZENE, https://www.cdc.gov/chemical-emergencies/chemical-fact-sheets/benzene.html.

[14] FDA ALERTS DRUG MANUFACTURERS TO THE RISK OF BENZENE CONTAMINATION IN CERTAIN DRUGS, https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs (emphasis added).

[15] Available at https://www.regulations.gov/document/FDA-2023-D-5408-0001.

"gels, creams, and lotions" have a "smooth, silky texture," that is due to carbomers. 88 Fed. Reg. 89703, 89704 (2023).[16]

37. As the FDA has noted, however, "[t]here are carbomers used as inactive ingredients"—including the carbomers used in the Products—"that are manufactured using benzene as a polymerization solvent." 88 Fed. Reg. at 89704.

38. In late December 2023, the FDA published a final guidance for industry titled "Reformulating Drug Products That Contain Carbomers Manufactured With Benzene." The FDA explained that the purpose of the guidance was "to provide recommendations to applicants and manufacturers on what tests should be performed and what documentation should be submitted or available to support the reformulation of drug products that use carbomers manufactured with benzene." 88 Fed. Reg. at 89704.

39. The FDA explained that United States Pharmacopeia ("USP")[17] "carbomer monographs[18] currently allow for unacceptable levels of benzene [as high as 5,000 parts per million], which raises safety concerns," and "requested that the USP omit (or remove) these monographs, and applicants and manufacturers may need to reformulate their drug products to avoid use of these carbomers." 88 Fed. Reg. at 89704.

40. The FDA noted the "immediate public health need to expedite the discontinuation of the use of carbomers manufactured with high levels of benzene in drug products," such as the Products. 88 Fed. Reg. at 89704. The FDA further acknowledged that "benzene is a known human

[16] Rachel Ann Tee-Melegrito, *What Are Carbomers?*, MEDICALNEWSTODAY (Dec. 22, 2023, https://www.medicalnewstoday.com/articles/carbomer.

[17] The USP is a compendium of drug information published annually "includes over 5000 quality standards for medicines, both chemical and biologic; active pharmaceutical ingredients (APIs); and excipients (inactive ingredients)." *See* AN OVERVIEW OF USP MONOGRAPHS https://www.usp.org/about/public-policy/overview-of-monographs (last visited 1/16/2025). The quality standards published therein "are used to help ensure the quality of medicines and their ingredients, and to protect the safety of patients." *Id.*

[18] A monograph is one of several quality standards for medications and articulates "the quality expectations for a medicine including for its identity, strength, purity, and performance. They also describe the tests to validate that a medicine and its ingredients meet these criteria." *See* AN OVERVIEW OF USP MONOGRAPHS, https://www.usp.org/about/public-policy/overview-of-monographs (last visited 1/16/2025).

carcinogen, and the Agency seeks to facilitate the transition away from using carbomers manufactured with high levels of benzene." *Id*.

41. The FDA's emergency guidance made clear that "benzene should not be employed in the manufacture of drug substances, excipients, and drug products" and, importantly, that "alternative grades of carbomers are available that are manufactured without the use of benzene." 88 Fed. Reg. at 89704.

III. DEFENDANTS KNOWINGLY MANUFACTURED AND SOLD PRODUCTS THAT WERE ALL CONTAMINATED WITH BENZENE

42. Despite this clear industry guidance and years of recalls of products containing benzene, Amneal knowingly manufactured and CVS knowingly sold the Products with a carbomer that contain[s] benzene above 2ppm. Because the benzene-containing carbomer is part of the Products' manufacturing process, *every Product* is contaminated with at least some amount of benzene.

43. There was no reason for Defendants to use a benzene-containing carbomer in the manufacture of the Products when carbomers formulated without benzene exist. Defendants' sole reason for doing so: "[a] carbomer made with benzene is a lot cheaper than one made without."[19] In other words, Defendants skimped out on safety for savings.

44. Recognizing the issues with its Products, Amneal "plans to submit testing data on its new formulation to the [FDA] by the end of [2024], and "[t]he company expects to bring the products to market before August 2025."[20] But this means that Defendants (i) know their Products have always contained benzene due to the carbomer, and (ii) plan to continue to sell the Products through at least August 2025.

45. Defendants, large and sophisticated corporations that manufacture and sell pharmaceutical drugs, knew or should have known of the risks of using a carbomer manufactured

[19] Alisa Chang et al., *Millions of Americans May be Getting Cancer-Causing Chemical in Generic Cold Medicine*.

[20] Anna Edney, Store-Brand Mucinex Maker to Move Away from Using Cancer-Causing Chemical, BNN BLOOMBERG (Aug. 13, 2024), https://www.bnnbloomberg.ca/business/company-news/2024/08/13/store-brand-mucinex-maker-to-move-away-from-using-cancer-causing-chemical/.

using benzene as a solvent in manufacturing the Products and the risks of benzene being present in the Products through internal testing of the finished dose of the Products. Indeed, Defendants were selling the Products even after the FDA's emergency guidance was issued and Plaintiff purchased the product approximately seven months following the FDA's emergency guidance. Therefore, Defendants knew or should have known about the dangers of benzene in carbomers included in the Products prior to selling them to Plaintiff and Class members.

46. As the manufacturer and seller of an over-the-counter drug product, Defendants had and have a duty to ensure that their Products did not and do not contain excessive (or any) level of benzene, including through regular testing, especially before injecting the Products into the stream of commerce for consumers to consume. But Defendants made no reasonable effort to test the Products for benzene, or to use alternative formulations that did not incorporate benzene. Nor did Defendants disclose to Plaintiff in any advertising or marketing that the Products contained benzene, let alone at levels that are multiples of the impurity limits set by the FDA.

47. Defendant also knew or should have known about the carcinogenic potential of benzene because it is classified as a Group 1 compound by the World Health Organization and the International Agency for Research on Cancer, meaning that it is "carcinogenic to humans."[21] As noted above, the FDA also classifies benzene as a "known human carcinogen," which Defendants should likewise know because their Products are regulated by the FDA.

48. Defendants also knew or should have known about high-profile recalls and citizens petitions related to the presence of benzene in drug and cosmetic products in recent years and should have been on alert to ensure that its Products did not contain benzene.

49. Accordingly, Defendants knowingly introduced dangerous and misbranded Products containing benzene into the U.S. market.

IV. THE PRESENCE OF BENZENE RENDERS THE PRODUCTS MISBRANDED AND ILLEGAL TO SELL

50. The Products are "drug" products that are regulated by the FDA pursuant to the federal Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as well as analogous

[21] https://monographs.iarc.who.int/wp-content/uploads/2019/07/Classifications_by_cancer_site.pdf.

state statutes and regulations, including California's Sherman Food, Drug, and Cosmetic Law, California Health & Safety Code §§ 109875, *et seq*. ("Sherman Law").

51. The Products are misbranded because their labeling is "false" and "misleading" because it does not disclose the presence of benzene, the fact that the carbomers in the Products were manufactured using benzene as a solvent, or that the manufacturing process involves the use of benzene and causes the Products to become contaminated with the same. 21 U.S.C. § 352(a)(1).

52. Over-the-counter medications, such as the Products, must contain "only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity." 21 C.F.R. § 330.1. Otherwise, they are considered misbranded. *Id.* Here, the benzene containing carbomer used by Defendants were not suitable inactive ingredients and are therefore misbranded.

53. A product that is "misbranded" cannot legally be manufactured, advertised, distributed, or sold. 21 U.S.C. § 331(a). Misbranded products thus have no economic value and are legally worthless.

54. California's Sherman Law expressly incorporates all drug labeling requirements set forth in the FDCA (*see* Cal. Health & Safety Code § 110100(a)), and further provides that any drug is misbranded if it does not conform to FDCA requirements.

55. Each of Defendants' violations of federal law and regulations also violates California's Sherman Law, including, but not limited to, the following sections:

(a) Section 110100 (adopting all FDA regulations as state regulations);

(b) Section 111330 (false or misleading labeling);

(c) Section 111400 (dangerous to health when used as suggested);

(d) Section 111440 (manufacture, sale, delivery, or holding of misbranded drug or device); and

(e) Section 111450 (reception or delivery of misbranded drug or device).

56. Defendants did not need to change the label of the Products to comply with their state law obligations. All Defendants needed to do was use a carbomer that did not contain high levels of benzene and thus would not result in benzene contamination in the finished Products—something Defendants are now doing.

57. Thus, the presence of benzene in the Products also renders the Products misbranded and therefore illegal and unfit for sale in trade or commerce.

V. DEFENDANTS' MISREPRESENTATIONS AND OMISSIONS INJURED PLAINTIFF AND CLASS MEMBERS

58. Defendants do not disclose to consumers that the Products contain benzene, nor do Defendants inform consumers of the cancer-causing properties of benzene. Defendants also do not disclose to consumers that the carbomer used in the manufacturing of the Products is made with benzene, and that the benzene in the carbomer is in excess of 2 ppm. And Defendants do not disclose to consumers that the manufacturing process of the Products causes the Products to become contaminated with benzene.

59. Defendants were required to disclose benzene as an "active ingredient" in the Products. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."

60. As noted above, exposure to benzene has the ability to cause cancer and trigger genetic mutation in humans, which affects the structure of the human body.[22] Therefore, benzene is an active ingredient by definition. Drugs (like the Products) with different and dangerous ingredients than their brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.

61. Further, the Products' labels refer to brand-name Mucinex, suggesting that the

[22] *See* https://pmc.ncbi.nlm.nih.gov/articles/PMC3271273/ (last visited 1/15/2025).

Products are the generic equivalent to brand-name Mucinex, but they are not because brand name Mucinex does not use carbomers containing benzene.

62. It was also unfair of Defendants to manufacture and sell a Product with a benzene-containing carbomer to consumers at full price, even though the presence of benzene renders the Products adulterated, misbranded, unsafe to use, and illegal to sell.

63. The presence of benzene in the Products is material to consumers given benzene's carcinogenic properties. If Plaintiffs and putative class members knew that the Products contained benzene and/or were defectively manufactured, Plaintiff and Class members would not have purchased the Products or they would have paid less for the Products than they did.

64. When Plaintiff and Class members purchased the Products, they did not know, and had no reason to know, that the Products contained the harmful carcinogen benzene. Not only would Plaintiff and Class members not have purchased the Products (or would have paid less for them) had they known the Products contained benzene, Plaintiff and Class members would also not have been capable of purchasing them if Defendants had done as the law required and tested the Products for benzene and other carcinogens and impurities, because the presence of benzene renders the Products misbranded and illegal to sell.

65. Consumers lack the ability to test or independently ascertain or verify whether a product contains unsafe substances, such as benzene, especially at the point of sale, and therefore must rely on Defendants to report truthfully and honestly what the Products contain on the Products' packaging or labels.

66. Yet, when consumers look at the Products' packaging, there is no mention of benzene. It is not listed in the ingredients section—which is where Defendant tells consumers to look to find out what is in the Products—nor is there any warning about the inclusion (or even potential inclusion) of benzene in the Products. Indeed, the fact that carbomers can be formulated without benzene—which brand name Mucinex is but the Products are not—supports the fact that consumers do not understand any of the ingredients to divulge the existence of benzene. This leads reasonable consumers to believe the Products do not contain benzene and that they will be equivalent to the

brand-name counterpart (here Mucinex).

67. Defendants' concealment was material and intentional because people are concerned with what is in the products that they are putting into their bodies. Consumers such as Plaintiff and Class Members make purchasing decisions based on the representations made on the Products' labeling, including the ingredients listed. This is especially true today, after numerous companies have issued recalls or resolved class action lawsuits concerning benzene contaminations in drug and cosmetic products.

68. Defendants know that if they had not mispresented or omitted that the Products contained benzene or the manufacturing process involved benzene, then Plaintiff and Class members would not have purchased the Products or would have paid less for them than they did.

CLASS ACTION ALLEGATIONS

69. Plaintiff seeks to represent a class defined as all persons in the United States who purchased the Products for personal or household use (the "Class"). Excluded from the Class are Defendants and any entities in which Defendants have a controlling interest, Defendants' agents and employees, any Judge and/or Magistrate Judge to whom this action is assigned and any member of such Judges' staffs and immediate families.

70. Plaintiff also seeks to represent a subclass of all Class members who purchased the Products for personal or household use in California (the "California Subclass"). Excluded from the California Subclass are Defendants and any entities in which Defendants have a controlling interest, Defendants' agents and employees, any Judge and/or Magistrate Judge to whom this action is assigned and any member of such Judges' staffs and immediate families.

71. The Class and the California Subclass are collectively referred to as the "Classes."

72. Subject to additional information obtained through further investigation and discovery, the foregoing definitions of the Classes may be modified, expanded, or narrowed by amendment to the complaint or narrowed at class certification.

73. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and

belief, Plaintiff reasonably estimates there are hundreds of thousands of members in the Class and tens of thousands of members in the California Subclass. Plaintiff does not know the exact number of members in the proposed Classes, but reasonably believes, based on the scale of Defendants' business, that the Classes are so numerous that individual joinder would be impracticable.

74. **Existence and Predominance of Common Questions of Law and Fact**. Common questions of law and fact exist as to all members of the Classes and predominate over any questions affecting only individual members of the Classes. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Products contain benzene;

(b) whether Defendants knew or should have known the Products contained benzene;

(c) whether Defendants are liable to Plaintiff and the Classes for unjust enrichment;

(d) Whether Defendants failed to disclose that the Products contain benzene;

(e) Whether Defendants misrepresented whether the Products contain benzene;

(f) whether Defendants violated the state consumer protection statutes alleged herein;

(g) whether Plaintiff and the Classes have sustained monetary loss and the proper measure of that loss;

(h) Whether a reasonable consumer would consider the presence of benzene in the Products to be material;

(i) Whether the presence of benzene in the Products renders the Products adulterated or misbranded;

(j) whether Plaintiff and the Classes are entitled to restitution and disgorgement from Defendants; and

(k) whether the marketing, advertising, packaging, labeling, and other promotional materials for the Products are deceptive.

75. **Typicality.** The claims of the representative Plaintiff are typical of the claims of the Classes in that the representative Plaintiff, like all members of the Classes, purchased the Products, which were worthless due to the presence of benzene, a harmful and carcinogenic chemical impurity.

The representative Plaintiff, like all members of the Classes, has been damaged by Defendants' misconduct in the very same way as the members of the Classes. Further, the factual bases of Defendants' misconduct are common to all members of the Classes and represent a common thread of misconduct resulting in injury to all members of the Classes.

76. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Classes. Plaintiff has retained counsel who are highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Classes. Plaintiff has no interests that are antagonistic to those of the Classes.

77. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by members of the Classes are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for members of the Classes, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Classes could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

78. In the alternative, the Classes may be certified because:

(a) the prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudication with respect to individual members of the Classes that would establish incompatible standards of conduct for the Defendants;

(b) the prosecution of separate actions by individual members of the Classes would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other members of the Classes not parties to the adjudications, or substantially impair or impede her ability to protect her interests; and/or

(c) Defendants have acted or refused to act on grounds generally applicable to the Classes as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Classes as a whole.

CAUSES OF ACTION

COUNT I
Breach Of the Implied Warranty Of Merchantability
(On Behalf of The Class And the California Subclass)

79. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

80. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the California Subclass against Defendants.

81. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers of the Products, impliedly warranted that the Products (i) would not contain elevated levels of benzene, (ii) are generally recognized as safe for human consumption, (iii) were manufactured in such a manner that they did not contain carcinogenic substances like benzene, and (iv) that the Products were not misbranded and were not illegal to sell.

82. Defendants breached the warranty implied in the contract for the sale of the Products because they could not pass without objection in the trade under the contract description, the Products were not of fair or average quality within the description, and the Products were unfit for their intended and ordinary purpose because the Products manufactured by Defendants contained elevated levels of carcinogenic benzene, and as such were not generally recognized as safe for human consumption. As a result, Plaintiff and Class and California Subclass members did not receive the goods as impliedly warranted by Defendants to be merchantable.

83. Plaintiff and Class and California Subclass members purchased the Products in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

84. The Products were not altered by Plaintiff or Class or California Subclass members.

85. The Products were defective when they left the exclusive control of Defendants.

86. Defendants knew that the Products would be purchased and used without additional testing by Plaintiff and Class and California Subclass members.

87. The Products were defectively manufactured and unfit for their intended purpose, and Plaintiff and Class and California Subclass members did not receive the goods as warranted.

88. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class and Subclass members have been injured and harmed because: (a) they would not have purchased the Products on the same terms if they knew that the Products contained harmful levels of benzene and are not generally recognized as safe for human consumption; and (b) the Products do not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

COUNT II
Unjust Enrichment
(On Behalf of The Class and the California Subclass)

89. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

90. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the California Subclass against Defendants.

91. Plaintiff and the Class and California Subclass conferred a benefit on Defendants in the form of monies paid to purchase Defendants' defective Products.

92. Defendants voluntarily accepted and retained this benefit.

93. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications contaminated with benzene and unfit for human use, it would be unjust and inequitable for the Defendant to retain it without paying the value thereof.

94. Plaintiff and Class and California Subclass members do not have an adequate remedy at law and plead their claim for unjust enrichment in the alternative to their legal claims. Legal remedies available to Plaintiff and Class and California Subclass members are inadequate because they are not equally prompt and certain and in other ways efficient as equitable relief. Damages are not equally certain as restitution because the standard that governs restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff fails to sufficiently adduce evidence to support an award of damages. Damages and restitution are not the same amount. Equitable relief, including restitution, entitles Plaintiff to

recover all profits from the wrongdoing, which may exceed the available damages at law.

COUNT III
Fraud
(On Behalf of The Class and the California Subclass)

95. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

96. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the California Subclass against Defendants.

97. Defendants engaged in material omissions of fact regarding the Products. Specifically, Amneal omitted the material fact that it used carbomers formulated with benzene as a solvent and included the benzene-laden carbomers into the finished dose of the Products. CVS omitted from consumers that the carbomers in its Products contained dangerous levels of benzene and were not the equivalent to brand name Mucinex.

98. Defendants' omissions of material fact, upon which Plaintiff and Class and California Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class and California Subclass members to purchase the Products.

99. Defendants knew or should have known that the Products contained dangerously high levels of benzene because the carbomers used in the Products were manufactured using monographs which used benzene as a solvent. As such, Defendants should have been aware of the risk of benzene in the Products and taken steps to mitigate the same but failed to do so.

100. Defendants were aware of prior recalls related to benzene in other drug and cosmetic products since at least 2021 but continued to manufacture and sell the Products even though they knew that benzene was used as a solvent in the manufacture of the Products.

101. During this time, Plaintiff and Class and California Subclass members were using the medication without knowing it contained dangerous levels of benzene.

102. The fraudulent actions of Defendants caused damage to Plaintiff and Class and California Subclass members, who are entitled to damages and other legal and equitable relief as a result.

103. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT IV
Violation Of California's Consumers Legal Remedies Act
California Civil Code § 1750, *et seq.*
(On Behalf of The California Subclass)

104. Plaintiff incorporates by reference and re-alleges herein all paragraphs alleged above.

105. Plaintiff brings this claim individually and on behalf of the members of the proposed California Subclass against Defendants.

106. Defendants violated Civil Code § 1770(a)(5) of the CLRA in that Defendants' acts and practices constitute omissions that the Products have characteristics, uses, and/or benefits which they do not.

107. Defendants violated Civil Code § 1770(a)(7) of the CLRA in that Defendants' acts and practices constitute omissions that the Products are of a particular quality, when they are not.

108. Defendants violated Civil Code § 1770(a)(9) of the CLRA in that Defendants' acts and practices constitute the advertisement of goods in question without the intent to sell them as advertised.

109. Defendants' acts and practices include their omissions about the Products containing benzene. Defendants knew the omitted fact was material to reasonable consumers given the risk of benzene to human health. Nevertheless, Defendants made such omissions on the Products labeling.

110. The presence of benzene in the Products impacts the central purpose of the Products because the central purpose of the Products is to improve health. By including benzene, the Products in fact harm consumers' health.

111. Plaintiff and the California Subclass Members have suffered harm as a result of these violations of the CLRA because they have incurred charges and/or paid monies for the Products that they otherwise would not have incurred or paid, and were unknowingly exposed to a significant and substantial health risk.

112. On September 5, 2025, Plaintiff's counsel sent Defendants a CLRA notice letter, which complied in all respects with California Civil Code § 1782(a). The letter was sent via certified

mail, return receipt requested, advising Defendants that it was in violation of the CLRA and demanding that they cease and desist from such violations and make full restitution by refunding the monies received therefrom. The letter stated that it was sent on behalf of all other similarly situated purchasers.

113. Defendants failed to remedy the issues raised in the notice letter. Accordingly, Plaintiff seeks damages from Defendants for their violations of the CLRA.

COUNT V
Violation Of California's Unfair Competition Law,
California Business & Professions Code §§ 17200, *et seq.*
(On Behalf of The California Subclass)

114. Plaintiff incorporates by reference and re-alleges herein all paragraphs alleged above.

115. Plaintiff brings this claim individually and on behalf of the members of the proposed California Subclass against Defendants.

116. By committing the acts and practices alleged herein, Defendants violated California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.* as to the Class, by engaging in unlawful, fraudulent, and unfair conduct.

117. Defendants violated the UCL's proscription against engaging in unlawful conduct as a result of its violations of (1) CLRA, Cal. Civil Code §§ 1770(a)(5), (a)(7), (a)(9), and (a)(16), and (2) California's Sherman Law as a result of selling Products that are misbranded.

118. Defendants' acts, omissions, and practices concerning the Products constitute "unlawful" business acts and practices in that they violate the FDCA and, by extension, California's Sherman Law, and implementing regulations including, at least, the following sections:

(a) Section 110100 (adopting all FDA regulations as state regulations);

(b) Section 111330 (false or misleading labeling);

(c) Section 111400 (dangerous to health when used as suggested);

(d) Section 111440 (manufacture, sale, delivery, or holding of misbranded drug or device); and

(e) Section 111450 (reception or delivery of misbranded drug or device).

119. Defendants' acts and practices described above violate the UCL's proscription against engaging in fraudulent conduct due to Defendants' material omissions regarding the Products, namely that the Products were manufactured using benzene as a solvent and contained high levels of benzene, as described more fully above.

120. Defendants' acts and practices described above also violate the UCL's proscription against engaging in unfair conduct in that Defendants manufactured a Product with a benzene-containing carbomer, even though benzene-free alternatives exist. Defendants then sold this Product at full price despite the fact that the benzene contamination renders the Products adulterated, misbranded, unsafe to use, and illegal to sell. Defendants' conduct is thus substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive and unscrupulous as the gravity of the conduct outweighs any alleged benefits.

121. Plaintiff and the other California Subclass members suffered a substantial injury by virtue of buying the Products in that they would not have purchased the Products absent Defendants' unlawful, fraudulent, and unfair marketing, advertising, packaging, and omission about the contaminated nature of its Products, or by virtue of paying an excessive premium price for the unlawfully, fraudulently, and unfairly marketed, advertised, packaged, and labeled Products.

122. Plaintiff and the other California Subclass members had no way of reasonably knowing that the Products they purchased were not as marketed, advertised, packaged, or labeled. Plaintiff and the other California Subclass members are not able to test for the presence of benzene in the Products. Thus, Plaintiff and the other California Subclass members could not have reasonably avoided the injury each of them suffered.

123. Plaintiff and the California Subclass lost money or property as a result of Defendants' UCL violations because: (a) they would not have purchased the Products on the same terms if they knew that the Products contained harmful levels of benzene, and are not generally recognized as safe for human consumption; and (b) the Products did not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

124. Pursuant to California Business and Professional Code § 17203, Plaintiff and the

California Subclass seek an order of this Court that includes, but is not limited to, an order requiring Defendants to: (a) provide restitution to Plaintiff and the other California Subclass members; (b) disgorge all profits obtained as a result of violations of the UCL; and (c) pay Plaintiff's and the Subclass' attorneys' fees and costs.

125. Plaintiff does not have an adequate remedy at law and pleads her claim under the UCL in the alternative to her legal claims. Legal remedies available to Plaintiff and Class Members are inadequate because they are not equally prompt and certain and in other ways efficient as equitable relief. Damages are not equally certain as restitution because the standard that governs restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff fails to sufficiently adduce evidence to support an award of damages. Damages and restitution are not the same amount. Equitable relief, including restitution, entitles Plaintiff to recover all profits from the wrongdoing, which may exceed the available damages at law.

126. Further, the "unlawful" prong of the UCL is the only way for Plaintiff to vindicate violations of the Sherman Act because the Sherman Act contains no private right of action. Similarly, the "unfair" prong of the UCL is the only way for Plaintiff to vindicate Defendants' violations relating to manufacturing practices to the extent Defendants are not permitted to disclose the same on the Products' label.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendants, as follows:

(a) For an order certifying the nationwide Class and the California Subclass under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiff as the representative for the Class and California Subclass, and naming Plaintiff's attorneys as Class Counsel;

(b) For an order declaring the Defendants' conduct violates the statutes referenced herein;

(c) For an order finding in favor of Plaintiff, the nationwide Class, and the California Subclass on all counts asserted herein;

(d) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

(e) For prejudgment interest on all amounts awarded;

(f) For an order of restitution and all other forms of equitable monetary relief; and

(g) For an order awarding Plaintiff and the Class and California Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: January 21, 2025

Respectfully submitted,

BURSOR & FISHER, P.A.

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